

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph at page 13, paragraph 1, with the following paragraph indicating the marked-up changes thereto.

In a further embodiment, an implant inserter can be used with the distractor to form a distraction and insertion system. Generally, the inserter can be similar to inserters known in the art, as well as the inserter 46 shown in FIGS. 7 and 8. As shown in FIGS. 7 and 8, the inserter 46 has proximal and distal ends 46a, 46b with a shaft 52 extending therebetween. While the proximal end 46a can have a variety of configurations, in an exemplary embodiment it can have a handle (or a portion thereof) fixedly or removably attached thereto.

Please replace the paragraph at page 14, paragraph 4, with the following paragraph indicating the marked-up changes thereto.

FIGS. 9 to 11 illustrate one embodiment of a distractor 112 that includes a paddle 122 having a proximal end 122a an angled distal end 122b, and thus providing an angled guide surface 122c. Many times, an implant is designed for placement at a certain angle of trajectory between the adjacent vertebrae 143 and/or a surgeon chooses a particular angle of placement in order to achieve desired fusion characteristics. Minimally invasive approaches 110 to the disk space provide well documented advantages, however, establishing a minimally invasive access portal 151 while sparing sensitive nerve tissues from contact and possible damage requires approach angles to the disk space that may not match the desired angle of placement of the implant. For example, a typical TLIF approach may take a 35° angle (plus or minus depending on the anatomy of a particular patient) while the desired angle for placement of the implant may be 45°. Providing an angled distal end 122b on the distractor paddle 122 allows the surgeon to carefully guide the implant during insertion to the desired angle with a reduced chance of contacting sensitive nerve tissue. While the distal end 122b of the paddle 122 can have a variety of angles as desired by the surgeon, in the illustrated embodiment, the distal end 122b of the paddle 122 has an angle of about 20°.

Please replace the paragraph at page 15, paragraph 2, with the following paragraph indicating the marked-up changes thereto.

In use, as an inserter (such as inserter 146) having a shaft 152 is slid distally along the shaft 114 of the distractor 112, the overhanging tabs 123a, 123b of the paddle 122 can slidably engage the outer edge surfaces of the implant 148. Once engaged, the implant 148 is guided along the length of the paddle 122. As the implant 148 approaches the distal end 122b of the paddle 122, the angled distal end 122b urges the implant 148 into the desired orientation within the intervertebral space 142.

Please replace the paragraph at page 15, paragraph 4, with the following paragraph indicating the marked-up changes thereto.

In use, extension of the shim 211 distally along the paddle 222 toward the paddle distal end 222b (generally by pushing on a proximal end or feature of the shim) beyond the guide elements 213 causes the shim to return to a curved shape. The angle of curvature of the shape memory metal shim 211 can be any angle that allows a surgeon to implant an spinal prosthesis into an intervertebral space 242, however in an exemplary embodiment, the curve of the shim 211 has an angle of about 20°. An implant 248 is then inserted into the intervertebral space 142 242 between adjacent vertebrae 241, 243 and, upon contact with the shim 211, is directed towards the desired placement angle within the intervertebral space 242. The shim 211 can also be retracted/straightened so that retraction of the distractor 212 does not displace the implant and so that retraction of the distractor does not disturb sensitive tissue.

Please replace the paragraph at page 16, paragraph 2, with the following paragraph indicating the marked-up changes thereto.

FIGS. 14 to 17 illustrate an alternate embodiment of a distractor 312 that includes a shaft 314 and has a paddle 322 having a shape memory metal shim 311 similar to metal shim 211 (described above), as well as extension shoulders 333a, 333b. While the extension shoulders 333a, 333b can have a variety of configurations, in an exemplary embodiment, they are slidably located on the paddle 322 (having proximal and distal ends 322a and 322b) and extendable from the superior and inferior sides thereof. However, in an alternate embodiment (not shown), a single extension shoulder can be formed on the paddle.

Please replace the paragraph at page 16, paragraph 3, with the following paragraph indicating the marked-up changes thereto.

In use, following insertion into an intervertebral space 342 and rotation of the paddle 322 to a distracting position, the distal movement of the shim 311, and in particular, contact between driving shoulders ~~313~~ 313a, 313b on the shim 311 and the extension shoulders 333a, 333b, drives the extension shoulders 333a, 333b upward and downward, respectively, to further distract the intervertebral space 342. While extension shoulders 333a, 323b can increase the height of the paddle 322 by any amount as desired by the surgeon to achieve and maintain a desired level of distraction of intervertebral space 342 between adjacent vertebrae 341, 343, in an exemplary embodiment, the paddle has a height of approximately 7mm and extension shoulders 333a, 333b increase the diameter of the paddle 322 by an amount up to approximately 4mm. By providing at least some of the distraction height by extension rather than rotation, a more sure placement of the distractor can be achieved with less movement within the cavity during distraction. Moreover, following extension of the extension shoulders 333a, 333b, the memory metal shim 311 extends beyond the distal end 322b of the paddle 322, and retains its curved shape, such that the surgeon can place the implant 348 into the cavity 342 at a desired angle.

Please replace the paragraph at page 17, paragraph 1, with the following paragraph indicating the marked-up changes thereto.

FIGS. 18 to 20 illustrate an alternate embodiment of a distractor 412 having a paddle 422 and an internal shim 409, as well as extension shoulders 433a, 433b for distracting intervertebral space 442 between adjacent vertebrae 441, 443. While the internal shim 409 can be formed in a variety of ways, as shown the internal shim 409 is formed within a sheath 407 surrounding the shaft 414 of the distractor 412. The internal shim 409 can also include an expansion mechanism such that, in use, and similar to the memory metal shim 211 discussed above, the internal shim 409 drives the extension shoulders 433a, 433b upward and downward, respectively, as the surgeon desires.

Please replace the paragraph at page 17, paragraph 2, with the following paragraph indicating the marked-up changes thereto.

Alternatively, as shown in FIGS. 21 to 23, the expanding shoulders 533a, 533b of a distractor 512 paddle 522 can be driven by an internal shim 509 having a linkage assembly 505 for distracting intervertebral space 542 between adjacent vertebrae 541, 543. While the linkage assembly 505 can be formed in a variety of ways, as shown the linkage assembly 505 is also formed within a sheath 507 surrounding the shaft 514 of the distractor 512. In use, similar to the embodiment above, the internal shim 509 can drive the linkage assembly 505 to control the height of the extension shoulders 533a, 533b as desired.

Please replace the paragraph at page 17, paragraph 3, with the following paragraph indicating the marked-up changes thereto.

FIGS. 24 to 26 illustrate another embodiment of a distractor 612 having an inserter arm 660 for positioning the distractor in the intervertebral space 642 between adjacent vertebrae 641, 643. Distractor 612 can include an internal shim 609 and extension shoulders 633a, 633b, similar to those as discussed above. The inserter arm 660 can be removed after placement of the distractor 612, and a cable 662 is left behind extending distally from the distractor 612.

Please replace the paragraph at page 18, paragraph 2, with the following paragraph indicating the marked-up changes thereto.

FIGS. 27 to 36 illustrate implant inserters having features that assist a surgeon in inserting an implant into an intervertebral space 742 adjacent to vertebral body 741 at a desired angle. At the outset it should be noted that the inserters of the embodiments described below can have features and can be used in a manner similar to that of inserter 46, discussed above. Moreover, depending upon the particular surgical assembly, the shafts of the inserters in the embodiments described below may or may not include a guide feature for slidably engaging with another surgical instrument.

Please replace the paragraph at page 19, paragraph 2, with the following paragraph indicating the marked-up changes thereto.

FIGS. 34 to 35 illustrates another embodiment of an inserter 946 that allows cable rotation of implant 948 in intervertebral space 942 with respect to vertebra 941 by a cable 962 that is linked to the implant 948. Inserter shaft 952 permits rotation of the implant in a hinge-like manner when the cable 962 is operated by the surgeon to drive the rotation. When the inserter shaft 952 is removed, the cable 962 must be disengaged from at least one of the implant 948 (in which case the cable 962 is removed with the shaft 952) or the shaft 952 (in which case the cable 962 is left behind with the implant 948). If the cable 962 is left behind, it can be formed, for example, from a bioabsorbable material.

Please replace the paragraph at page 19, paragraph 3, with the following paragraph indicating the marked-up changes thereto.

FIG. 36 illustrates an exemplary embodiment of an implant driver 1346 that can be used with inserter 946 to permit rotation of the implant 1348. The implant 1348 includes an external boss feature 1387 that is held between two inserter tabs 1388a, 1388b extending from shaft 1352. The inserter tabs 1388a, 1388b can have a variety of configurations, however in an exemplary embodiment, they include an inserter tab movement mechanism that allows a surgeon to adjust the angulation of the implant 1348, for example by using cable 962 from the embodiment of FIGS. 34 and 35. In one sense, external boss feature 1387 and tabs 1388a, 1388b are the inverse of cavity 885 and inserter driver 881 from the embodiment of FIGS. 32 and 33. Both configurations can allow angulation of the implant, but by contact with external and internal surfaces of the implant respectively.

Please replace the paragraph at page 20, paragraph 2, with the following paragraph indicating the marked-up changes thereto.

FIGS. 38 and 39 show one embodiment of a ratchet gun 1180 that includes distraction paddles 1184a, 1184b for inserting a prosthesis 1048 in an intervertebral space 1042 adjacent vertebral body 1041. While the distraction paddles 1184a, 1184b can have a variety of configurations known in the art, in an exemplary embodiment, they extend from arms 1181a, 1181b on the distal most end of the ratchet gun and are shaped and sized such that they fit against the inner surfaces of the superior and inferior vertebrae 1141, 1143. As this embodiment includes paddle distractors, inserter 1180 is not intended to be guided by a paddle distractor as with embodiments described above.

Please replace the paragraph at page 20, paragraph 4, with the following paragraph indicating the marked-up changes thereto.

As further shown in FIGS. 40 and 41, a ratchet gun inserter 1280, similar to ratchet gun inserter 1180, can include a rotating inserter 1247 on shaft 1246 that can have any configuration as described herein (above in FIGS. 27 to 36) for inserting prosthesis 1248. Alternatively, as shown in FIGS. 42 and 43, the ratchet gun ~~1280~~ 1380 can include a memory metal shim ~~1211~~ 1311, such as that described in FIGS. 12 and 13 above to allow insertion of an implant 1348 at a desired angulation in the intervertebral space 1342 between adjacent vertebrae 1341, 1343.